

Docket 14231-2

2

PATENT

a first sensor that measures one or more elastic parameters associated with the target site drawn from a group consisting of a Young's modulus, a bulk modulus and a Poisson's ratio associated with the target site;

a second sensor that measures one or more thermal parameters, drawn from a group consisting of local temperature, thermal conductivity and specific heat capacity associated with the target site;

a third sensor that measures optical reflectance  $OR(\lambda;meas)$  of a selected region of the target site for one or more selected wavelength ranges;

[a fourth sensor that measures a selected characteristic of a margin of the target site;]

a [fifth] fourth sensor that measures amount of blood flow adjacent to or within the target site;

a [sixth] fifth sensor that measures interstitial fluid pressure adjacent to or within the target site;

[a seventh sensor that measures vascular size and/or vascular density associated with the target site;]

[an eighth] a sixth sensor that measures at least one of pO<sub>2</sub> and pCO<sub>2</sub> associated with the target site;

a [ninth] seventh sensor that measures local pH associated with a selected portion of the target site; and

[a tenth] an eighth sensor that measures at least one of an electrical parameter and a bioimpedance parameter associated with a selected portion of the target site;

wherein said probe is configured to measure at least one property drawn from:

a selected characteristic of a margin of the target site;

vascular size associated with the target site; and

vascular density associated with the target site.

clean copy  
has a period(.)

Docket 14231-2

3

PATENT

\*2 (twice amended). The system of claim 1, wherein at least one of said [two] plurality of sensor measurements is combined with at least one additional measurement that is drawn from a group of measurements, performed adjacent to or within said target site, consisting of lymph node samples, [mammograms, ultrasound scans, NMRI scans, CAT scans,] estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern.

B | \*3 (twice amended). The system of claim 1, wherein at least one of said [two] plurality of sensor measurements is combined with at least one additional information item that is drawn from a group consisting of (1) at least one medical condition that said animal has exhibited and (2) at least one medical condition that a family member of said animal has exhibited.

\*4 (twice amended). The system of claim [1] 19, wherein, when at least one of said sensors provides a measurement value that is non-normal and does not fall within said corresponding range of values for said normal target site, said database and analyzer provides at least one disease or malady of said target site that is consistent with [each] at least one of [said] the sensor non-normal measurement values.

\*5 (twice amended). The system of claim 19, wherein said analyzer comprises a neural net device that receives and processes said measurement from said plurality of [at least two] sensors and provides at least one processed measurement value that can be compared with said corresponding range of values for said normal target site.

6. The system of claim 5, wherein said neural net device performs a radial basis neural network analysis.

Docket 14231-2

4

PATENT

7. The system of claim 5, wherein said neural net device performs a backpropagation neural network analysis.

\*8 (twice amended). The system of claim 1, wherein at least one of said [two] plurality of sensors is used to navigate said probe to a selected location adjacent to or within said target site.

\*9 (twice amended). A method for performing one or more relevant measurements at a target site in an animal body, the method comprising:

*BJ*  
providing a probe that can be inserted into a body adjacent to or within a target site and that comprises [at least two] a plurality of sensors drawn from:

a first sensor that measures one or more elastic parameters associated with the target site drawn from a group consisting of a Young's modulus, a bulk modulus and a Poisson's ratio associated with the target site;

a second sensor that measures one or more thermal parameters, drawn from a group consisting of local temperature, thermal conductivity and specific heat capacity associated with the target site;

a third sensor that measures optical reflectance  $OR(\lambda; meas)$  of a selected region of the target site for one or more selected wavelength ranges;

[a fourth sensor that measures a selected characteristic of a margin of the target site;]

an [fifth] fourth sensor that measures amount of blood flow adjacent to or within the target site;

a [sixth] fifth sensor that measures interstitial fluid pressure adjacent to or within the target site;

[a seventh sensor that measures vascular size and/or vascular density associated with the target site;]

[an eighth] a sixth sensor that measures at least one of pO<sub>2</sub> and pCO<sub>2</sub> associated with the target site;

Docket 14231-2

5

PATENT

a [ninth] seventh sensor that measures local pH associated with a selected portion of the target site; and

[a tenth] an eighth sensor that measures at least one of an electrical parameter and a bioimpedance parameter associated with a selected portion of the target site;

wherein said probe is configured to measure at least one property drawn

from:

a selected characteristic of a margin of the target site;

vascular size associated with the target site; and

vascular density associated with the target site

\*10 (twice amended). The method of claim 9, further comprising combining [said] at least one of said [two] plurality of sensor measurements with at least one additional measurement, performed adjacent to or within said target site, consisting of lymph node samples, [mammograms, ultrasound scans, NMRI scans, CAT scans,] estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern.

\*11 (twice amended). The method of claim 9, further comprising combining at least one of said [two] plurality of sensor measurements with at least one additional information item that is drawn from a group consisting of (1) at least one medical condition that said animal has exhibited and (2) at least one medical condition that a family member of said animal has exhibited.

\*12 (twice amended). The method of claim 18, further comprising:

when each of at least one of said sensors provides a measurement value that is non-normal and does not fall within said corresponding range of values for said normal target site, said computer is programmed to provide at least one disease or malady of said target site that is consistent with [each of the at least two] at least one of the sensor non-normal measurement values.

Docket 14231-2

6

PATENT

\*13 (twice amended). The method of claim [18] 20, further comprising providing said analyzer with a neural net device that receives and processes said measurement from [said] at least one of said plurality of sensors and provides a processed measurement value that can be compared with said corresponding range of values for said normal target site.

*B2*  
14. The method of claim 13, further comprising choosing said neural net device to perform a radial basis neural network analysis.

15. The method of claim 13, further comprising choosing said neural net device to perform a backpropagation neural network analysis.

*B3*  
\*16 (twice amended). The method of claim 9, further comprising using at least one of said plurality of sensors to navigate said probe to a selected location adjacent to or within said target site.

*B3*  
\*17 (amended). The system of claim 1, wherein at least one of said [at least two] plurality of sensors is said third sensor that measures said optical reflectance, using at least one optical fiber that transports an image of a selected portion of said selected region of said target site.

*B3*  
\*18 (amended). The method of claim 9, further comprising providing, as at least one of said [at least two] plurality of sensors is said third sensor and measuring said optical reflectance by using at least one optical fiber that transports an image of a selected portion of said selected region of said target site.

\*19 (amended). The system of claim 1, further comprising a database and analyzer that receives and compares each of said measurements made by said probe with a corresponding range of values that is representative of a normal target site

Docket 14231-2

7

PATENT

and, for [each] at least one of said sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one medical condition of said target site that is generally consistent with [said] the sensor non-normal measurement.

\*20 (amended). The method of claim 9, further comprising providing a database and analyzer, including a computer that is programmed to receive and compare each of said measurements made by said probe with a corresponding range of values that is representative of a normal target site and, for [each] at least one of said [probe] sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one [disease or malady of the] medical condition of said target site that is consistent with s [said probe] the non-normal sensor measurement.

43  
\*41 (new). The system of claim 19, wherein said database and analyzer receives and compares first and second sensor measurements made by said probe with first and second measurement ranges, respectively, for a normal site and, when said first and said second sensor measurements are non-normal and do not fall within corresponding first and second measurement ranges, respectively, for a normal site, said database and analyzer (i) provides first and second medical conditions that are consistent with said first and second sensor non-normal measurements, respectively, and (ii) determines if a third medical condition is present that is consistent with the first medical condition and with the second medical condition.

44  
\*42 (new). The method of claim 20, comprising further programming said computer to receive and compare first and second sensor measurements made by said probe with first and second measurement ranges, respectively, for a normal site and, when said first and said second sensor measurements are non-normal and do not fall within corresponding first and second measurement ranges, respectively, for

Docket 14231-2

8

PATENT

a normal site, (i) to provide first and second medical conditions that are consistent with said first and second sensor non-normal measurements, respectively, and (ii) to determine if a third medical condition is present that is consistent with the first medical condition and with the second medical condition.

45

\*43 (new). The system of claim 1, wherein at least one of said sensor measurements is combined with at least one additional measurement that is drawn from a supplemental group of measurements, performed adjacent to or within said target site, consisting of lymph node samples, mammograms, ultrasound scans, NMRI scans, CAT scans, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern, further comprising a database and analyzer that receives and analyzes the at least one supplemental group measurement using fuzzy logic.

46

*PLC* | \*44 (new). The system of claim 1, wherein at least one of said sensor measurements is combined with at least one additional measurement that is drawn from a group of measurements, performed adjacent to or within said target site, consisting of mammograms, ultrasound scans, NMRI scans and CAT scans.

47

\*45 (new). The method of claim 9, further comprising:  
combining at least one of said sensor measurements with at least one additional measurement, performed adjacent to or within said target site, consisting of lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern;  
and

providing a database and analyzer that receives and analyzes the at least one supplemental group measurement using fuzzy logic.

48

\*46 (new). The method of claim 9, further comprising combining at least one of said sensor measurements with at least one additional measurement, performed

Docket 14231-2

9

PATENT

adjacent to or within said target site, consisting of mammograms, ultrasound scans, NMRI scans and CAT scans.

49  
\*47 (new). A system for performing one or more relevant measurements at a target site in an animal body, the system comprising:

a probe that can be inserted into a body adjacent to or within a target site and that comprises at least one of a group of sensors drawn from:

a first sensor that measures one or more elastic parameters associated with the target site drawn from a group consisting of a Young's modulus, a bulk modulus and a Poisson's ratio associated with the target site;

a second sensor that measures one or more thermal parameters, drawn from a group consisting of local temperature, thermal conductivity and specific heat capacity associated with the target site;

a third sensor that measures optical reflectance  $OR(\lambda;meas)$  of a selected region of the target site for one or more selected wavelength ranges;

a fourth sensor that measures amount of blood flow adjacent to or within the target site;

a fifth sensor that measures interstitial fluid pressure adjacent to or within the target site;

a sixth sensor that measures at least one of pO<sub>2</sub> and pCO<sub>2</sub> associated with the target site;

a seventh sensor that measures local pH associated with a selected portion of the target site; and

an eighth sensor that measures at least one of an electrical parameter and a bioimpedance parameter associated with a selected portion of the target site; and

a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that is non-normal and does not fall within the corresponding range

Docket 14231-2

10

PATENT

of values for a normal target site, the database and analyzer provides at least one medical condition of said target site that is generally consistent with the sensor non-normal measurement,

50

\*48 (new). The system of claim 47, wherein at least one of said group of sensor measurements is combined with at least one additional measurement that is drawn from a group of measurements, performed adjacent to or within said target site, consisting of lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern.

51

B4 \*49 (new) The system of claim 47, wherein, when at least one sensor provides a measurement value that is non-normal and does not fall within said corresponding range of values for the normal target site, the database and analyzer provides at least one disease or malady of the target site that is consistent with at least one of the sensor non-normal measurement values.

52

\*50 (new). A method for performing one or more relevant measurements at a target site in an animal body, the method comprising:

providing a probe that can be inserted into a body adjacent to or within a target site and that comprises at least one of a group of sensors drawn from:

a first sensor that measures one or more elastic parameters associated with the target site drawn from a group consisting of a Young's modulus, a bulk modulus and a Poisson's ratio associated with the target site;

a second sensor that measures one or more thermal parameters, drawn from a group consisting of local temperature, thermal conductivity and specific heat capacity associated with the target site;

a third sensor that measures optical reflectance  $OR(\lambda; meas)$  of a selected region of the target site for one or more selected wavelength ranges;

Docket 14231-2

11

PATENT

a fourth sensor that measures amount of blood flow adjacent to or within the target site;

a fifth sensor that measures interstitial fluid pressure adjacent to or within the target site;

a sixth sensor that measures at least one of pO<sub>2</sub> and pCO<sub>2</sub> associated with the target site;

a seventh sensor that measures local pH associated with a selected portion of the target site; and

an eighth sensor that measures at least one of an electrical parameter and a bioimpedance parameter associated with a selected portion of the target site; and

*Bu*  
providing a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one medical condition of said target site that is generally consistent with the sensor non-normal measurement,

\*51 (new) The method of claim 50, further comprising combining at least one of said first group of sensor measurements with at least one additional measurement that is drawn from a group of measurements, performed adjacent to or within said target site, consisting of lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern.

\*52 (new) The method of claim 50, wherein, when at least one sensor provides a measurement value that is non-normal and does not fall within said corresponding range of values for the normal target site, the database and analyzer

Docket 14231-2

12

PATENT

*B* provides at least one disease or malady of the target site that is consistent with at least one of the sensor non-normal measurement values.

Docket 14231-2

13

PATENT

**Reply To Examiner's Remarks**

Claims 1-20, as amended, and new claims 41-50 are pending for consideration.

The Applicant confirms an election to cancel claims 21-40 and to proceed with prosecution of claims 1-20, as amended.

The Applicant herewith agrees to submit an executed Terminal Disclaimer for U.S. Patent No. 6,109,270, issued to Mah et al, as required by the Examiner.

The Examiner rejects claims 1-20 under 35 U.S.C. 102(e) as anticipated by the disclosures in U.S. Patent No. 6,109,270, issued to Mah et al. The Examiner rejects claims 1 and 9 under 35 U.S.C. §102(e) as anticipated by the disclosures in U.S. Patent No. 6,186,945, issued to Gardosi. The Examiner rejects claims 1-4, 9-11 and 19-20 under 35 U.S.C. §103(a) as obvious in view of the combined disclosures of the Gardosi patent and U.S. Patent No. 6,093,151, issued to Shine et al.

In one embodiment, the Mah et al patent discloses a multi-mode instrument for identification and characterization of tissues, using a neural net learning process and using one or more of the following devices or sensors:

- a strain gauge,
- a wick in needle pressure sensor,
- a laser Doppler blood flow sensor,
- an ultrasound probe,
- an endoscope,
- an oxygen partial pressure sensor,
- a carbon dioxide partial pressure sensor,
- an optical (reflectance) sensor,
- a temperature sensor,
- an ion specific sensor,
- a microelectrode,
- a tissue ablation sensor, and
- an effector.

Docket 14231-2

14

PATENT

In one embodiment, the probe is housed in a movable cannula, and moves relative to the cannula, within the animal's body. Each of the sensors or devices on the probe (except the effector) measures a mechanical, electrical, biological, chemical or thermal quantity as the cannula/probe assembly moves through the animal's body, and a measured value for that quantity is compared with a normal range of values for that quantity. If the measured value falls outside the normal range for that quantity, motion of the cannula/probe may be terminated and the tissue or other organism that produced the measured value may be examined.

Claim 1, as amended, of the subject patent application recites a system for performing one or more relevant sensor measurements at or near a target site in an animal's body. The system comprises:

a probe that can be inserted into a body adjacent to or within a target site and that comprises a plurality of sensors drawn from:

a first sensor that measures one or more elastic parameters associated with the target site drawn from a group consisting of a Young's modulus, a bulk modulus and a Poisson's ratio associated with the target site;

a second sensor that measures one or more thermal parameters, drawn from a group consisting of local temperature, thermal conductivity and specific heat capacity associated with the target site;

a third sensor that measures optical reflectance  $OR(l;meas)$  of a selected region of the target site for one or more selected wavelength ranges;

a fourth sensor that measures amount of blood flow adjacent to or within the target site;

a fifth sensor that measures interstitial fluid pressure adjacent to or within the target site;

a sixth sensor that measures at least one of  $pO_2$  and  $pCO_2$  associated with the target site;

a seventh sensor that measures local pH associated with a selected portion of the target site; and

Docket 14231-2

15

PATENT

an eighth sensor that measures at least one of an electrical parameter and a bioimpedance parameter associated with a selected portion of the target site;

where the probe is configured to measure at least one property drawn from: a selected characteristic of a margin of the target site; vascular size associated with the target site; and vascular density associated with the target site.

Claim 2, as amended, of the application depends upon claim 1 and further recites that at least one of the plurality of sensor measurements is combined with at least one additional measurement that is drawn from a group of measurements, performed adjacent to or within the target site, consisting of lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern.

Claim 19, as amended, of the application depends upon claim 1 and further recites a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one medical condition of the target site that is generally consistent with the sensor non-normal measurement.

Claim 41 depends upon claim 19 and further recites that the database and analyzer receives and compares the first and second sensor measurements made by the probe with first and second measurement ranges, respectively, for a normal site and, when the first and the second sensor measurements are non-normal and do not fall within corresponding first and second measurement ranges, respectively, for a normal site, the database and analyzer (i) provides first and second medical conditions that are consistent with the first and second sensor non-normal measurements, respectively, and (ii) determines if a third medical condition is present that is consistent with the first medical condition and with the second medical condition.

Docket 14231-2

1 6

PATENT

Claim 4, as amended, of the application depends upon claim 19 and further recites that, when at least one of the sensors provides a measurement value that is non-normal and does not fall within the corresponding range of values for the normal target site, the database and analyzer provides at least one disease or malady of the target site that is consistent with at least one of the sensor non-normal measurement values.

Claim 8, as amended, of the application depends upon claim 1 and further recites that at least one of the plurality of sensors is used to navigate the probe to a selected location adjacent to or within the target site.

Claims 9, 10, 20, 12, 42 and 16 are method claims that are parallel to the system claims 1, 2, 19, 41, 4 and 8, respectively.

The Mah et al patent does not teach or suggest provision of a probe configured to measure at least one of: a selected characteristic of a margin of the target site; vascular size associated with the target site; and vascular density associated with the target site. None of these measurements, or the devices to make such measurements, is taught or suggested by the Mah et al patent.

The Mah et al patent does not teach or suggest, as is recited in claim 2, combining at least one of the plurality of sensor measurements with at least one additional measurement that is drawn from the following group of measurements, performed adjacent to or within the target site: lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern. The Mah et al patent is concerned with use of ultrasound scans, CAT scans, NMRI scans and the like.

The Mah et al patent does not teach or suggest, as recited in claim 19, providing a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one

Docket 14231-2

17

PATENT

medical condition of the target site that is generally consistent with the sensor non-normal measurement(s).

The Mah et al patent does not teach or suggest, as further recited in claim 41, providing a database and analyzer that receives and compares first and second sensor measurements made by the probe with first and second measurement ranges, respectively, for a normal site and, when the first and the second sensor measurements are non-normal and do not fall within corresponding first and second measurement ranges, respectively, for a normal site, the database and analyzer (i) provides first and second medical conditions that are consistent with the first and second sensor non-normal measurements, respectively, and (ii) determines if a third medical condition is present that is consistent with the first medical condition and with the second medical condition.

The Mah et al patent does not teach or suggest, as recited in claim 4, providing a system configured so that, when at least one of the sensors provides a measurement value that is non-normal and does not fall within the corresponding range of values for the normal target site, the database and analyzer provide at least one disease or malady of the target site that is consistent with at least one of the sensor non-normal measurements.

The Mah et al patent distinguishes between measurements in a normal range and outside a normal range, as the cannula/probe moves into the brain or other organ or tissue. When one or more non-normal range measurements is received, movement of the cannula/probe is halted, but no attempt is made to determine a medical condition, or a disease or malady at the target site, that is consistent with this measurement(s). The Mah et al patent discloses classifying a tissue or organ and comparing one or more measured values to a normal range of values. Claim 4 recites consulting a database and determining at least one medical condition, disease or malady that is consistent with one, two or more measured values in non-normal ranges, which is not taught or suggested by, and is not an obvious extension of what is disclosed in, the Mah et al patent.

Docket 14231-2

18

PATENT

The Mah et al patent does not teach or suggest, as recited in claim 8, configuring the system so that at least one of the plurality of sensors is used to navigate the probe to a selected location adjacent to or within the target site. The ~~Mah et al patent discloses halting motion of the cannula/probe, based on comparison~~ of one or more measured values with a normal range or ranges for that value or values. The Mah et al patent does not teach or suggest using one or more of the sensors to navigate the cannula/probe to a selected location within the animal's body.

New claim 47 recites a system for performing one or more relevant measurements at a target site in an animal body, wherein the system comprises a probe that can be inserted into a body adjacent to or within a target site and that comprises at least one of a group of sensors drawn from:

a first sensor that measures one or more elastic parameters associated with the target site drawn from a group consisting of a Young's modulus, a bulk modulus and a Poisson's ratio associated with the target site;

a second sensor that measures one or more thermal parameters, drawn from a group consisting of local temperature, thermal conductivity and specific heat capacity associated with the target site;

a third sensor that measures optical reflectance OR(1;meas) of a selected region of the target site for one or more selected wavelength ranges;

a fourth sensor that measures amount of blood flow adjacent to or within the target site;

a fifth sensor that measures interstitial fluid pressure adjacent to or within the target site;

a sixth sensor that measures at least one of pO<sub>2</sub> and pCO<sub>2</sub> associated with the target site;

a seventh sensor that measures local pH associated with a selected portion of the target site; and

an eighth sensor that measures at least one of an electrical parameter and a bioimpedance parameter associated with a selected portion of the target site; and

Docket 14231-2

19

PATENT

a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one medical condition of said target site that is generally consistent with the sensor non-normal measurement.

New claim 49 recites that when at least one sensor provides a measurement value that is non-normal and does not fall within said corresponding range of values for the normal target site, the database and analyzer provides at least one disease or malady of the target site that is consistent with at least one of the sensor non-normal measurement values.

As noted in the preceding discussion of claim 19, the Mah et al patent does not teach or suggest a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that is non-normal and does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one medical condition of the target site that is generally consistent with the sensor non-normal measurement. New claim 47 recites these features and is not obvious from the disclosures in the Mah et al patent.

New claim 48, dependent upon claim 47, further recites that at least one of the first group of sensor measurements is combined with at least one additional measurement that is drawn from a second group of measurements, performed adjacent to or within the target site, consisting of lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern. As noted in the preceding discussion of claim 2, claim 48 is not obvious from the disclosures of the Mah et al patent.

Docket 14231-2

20

PATENT

The Gardosi patent discloses a fetal probe, intended to be inserted into a womb through a woman's cervix, to sense a fetal heart beat. The probe is positioned against the fetus, and an inflatable sac at the distal end of the probe urges the probe against the fetus to permit ECG and/or oximetry measurements to be made. The probe includes a flexible, sharp-tipped trochar to perforate one or more membranes associated with the fetus.

The Shine et al patent discloses a maternal and fetal monitor, intended to be inserted against or into a pregnant woman's body (i) to measure maternal blood pressure, (ii) to sense initiation of uterine contractions, (iii) to prevent blood pressure measurement when a uterine contraction is sensed, and (iv) to re-initiate a blood pressure measurement after a uterine contraction is terminated. The monitor includes a blood pressure measuring device (fetal and maternal), a uterine contraction sensor, sensors for measuring fetal and maternal oximetry and ECG, an ultrasound source, and a data recording mechanism.

The combined disclosures of the Mah et al patent, the Gardosi patent and the Shine et al patent do not teach or suggest: (1) providing a probe configured to measure at least one of a selected characteristic of a margin of the target site, vascular size associated with the target site, and vascular density associated with the target site, as recited in claim 1; (2) combining at least one of the at least two sensor measurements with at least one additional measurement that is drawn from a group of measurements, performed adjacent to or within the target site, consisting of lymph node samples, estimation of target site size, estimation of target site shape, estimation of target site surface roughness and estimation of calcification pattern, as recited in claim 2; (3) provision of a database and analyzer that receives and compares each of the measurements made by the probe with a corresponding range of values that is representative of a normal target site and, for at least one of the sensor measurements that does not fall within the corresponding range of values for a normal target site, the database and analyzer provides at least one medical condition of the target site that is generally consistent with at least one of the sensor non-normal measurement(s), as recited in claims 19, 47 and 50; (4) configuring the

Docket 14231-2

21

PATENT

database and analyzer, which receives and compares first and second sensor measurements made by the probe with first and second measurement ranges for a normal site so that, when the first and the second sensor measurements do not fall within corresponding first and second measurement ranges, respectively, for a normal site, the database and analyzer (i) provides first and second medical conditions that are consistent with the first and second sensor non-normal measurements, respectively, and (ii) determines if a third medical condition is present that is consistent with the first medical condition and with the second medical condition, as recited in claim 41; (5) configuring the database and analyzer so that, when at least one of the sensors provides a measurement value that does not fall within the corresponding range of values for the normal target site, the database and analyzer provide at least one disease or malady of the target site that is consistent with at least one of the sensor non-normal measurements, as recited in claim 4; and (6) using at least one of the at least two sensors to navigate the probe to a selected location adjacent to or within the target site, as recited in claim 8.

It would not have been obvious, from these combined disclosures, to provide the features set forth in (1), (2), (3), (4), (5) and/or (6), recited in claims 1, 2, 19, 41, 4, 8, and/or 47-52, in the preceding paragraph, because the focus of the Mah et al patent is in other directions, not associated with and not parallel to these features.

Claims 3, 5-7, 17, 43 and 44 depend upon claim 1 or claim 19, as amended, and are believed to be allowable if claim 1 or claim 19 is allowable.

Claims 9, 10, 20, 42, 12, 16 , 50-52 are method claims that are parallel to the system claims 1, 2, 19, 41, 4 and 47-49, respectively, and are believed to be allowable for the reasons discussed in connection with claims 1, 2, 19, 21, 4 and 47 - 49. Claims 11, 13-15, 18 and 45-46 depend upon claim 9, as amended, or claim 20, and are believed to be allowable if claim 9 or claim 20 is allowable.

For the foregoing reasons, the Applicant believes that claims 1-20, as amended, and new claims 41-52 are allowable and requests that the Examiner pass the application, including claims 1-20 and 41-52, to issue as a U.S. patent.

Docket 14231-2

22

PATENT

Respectfully Submitted,



Date: February 21, 2003

Robert M. Padilla

Registration No. 38987

Patent representative for Applicants